ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

Douglas L. Sporn 0611 '00 SEP 26 A9:15
Divisional Vice President
Corporate Regulatory Affairs
D-387, AP6C-1
Telephone: (847) 937-7986

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-3106
E-mail: doug.sporn@abbott.com

September 25, 2000

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: FDA's Medical Product Reporting Program
Docket No. 96N-0393

Dear Sir:

Abbott Laboratories is pleased to have the opportunity to provide comments on the Notice for MedWatch published on July 26, 2000, in the *Federal Register*. We propose the attached comments and suggestions to help strengthen the utility of the MedWatch Program.

On behalf of the 57,000 Abbott employees who help produce healthcare products marketed in more than 130 countries, we thank you for your consideration of our comments.

Sincerely,

Douglas L. Sporn

Douglas L.Sporn

(Signed for Douglas L. Sporn in his absence)

96N-0393

C27

MEDWATCH COMMENT RESPONSE
ABBOTT LABORATORIES
September 25, 2000

SPECIFIC COMMENTS

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

Yes, Abbott areas utilizing the MedWatch 3500A form agree that the collection of adverse event information is necessary for the proper performance of FDA's functions. The form is fairly well established and does not require significant revisions.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

The burden of collection appeared specific to device handling rather than adverse event reporting for drugs. No comment was made with respect to device reporting.

The burden of collection for drug adverse event reporting does not appear to be related to the MedWatch 3500A collection form, but is an accepted responsibility as defined by the CFR, March 1992 guideline, and August 1997 Guidance For Industry.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

The following suggestions for enhancing the quality, utility, and clarity of the information collected:

- Providing more detailed instruction for MedWatch use (example: defining use for Section B2, B4, date fields).

- Updating the March 1992 Guidelines to incorporate MedWatch form use. There are specific details in the March 1992 Guidelines that discuss handling of special circumstances such as: reporting multiple suspect drugs, reporting/identifying follow-up information. As such, it is unclear how much of previous guidelines should be applied to current practice.

- FDA industry-wide assessment of consistency of MedWatch field use for both devices and drugs. The assessment should be separate since the instructions for devices and drugs differ. A document outlining consistent and accurate use of the MedWatch 3500A form should follow this assessment.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The following suggestions may assist in minimizing the burden of collection of information on respondents -

- Guidelines for internet and electronic communications as means for adverse event reporting, including:

    1. Related compliance expectations to Part 11 and CFR.

    2. How August 1997 Guidance for Industry definitions of identifiable patient and identifiable reporter apply.

- Expand public education regarding post marketed adverse event reporting that includes training programs. These could be focused to understand the necessity of collecting adverse events and knowledge of the type of data requested may enhance data acquisition for voluntary reporters and required industry practices.

- Provide an opportunity for industry to review the "Menu option on Internet site to facilitate the collection of Baseline information" prior to implementation.

9

52

FedEx USA Airbill

FedEx Tracking Number 822809626860

SPG11

Form I.D. No. 0215

Recipient's Cop

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 9/25/00 FedEx Tracking Number 822809626860

Sender's Name Doug Sporn Phone 847 937-0882

Company ABBOTT LABS (847) 937-7986

Address 100 ABBOTT PARK RD Dept./Floor/Suite/Room

City ABBOTT PARK State IL ZIP 60064

2 Your Internal Billing Reference

3 To

Recipient's Name Dockets Management Branch Phone 301 827-6860

Company HFA-305, Food and Drug Administration

Address 5630 Fishers Lane Room 1061

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Dept./Floor/Suite/Room

City Rockville State MD ZIP 20852

8228 0962 6860

0152761152

4a Express Package Service *Packages up to 150 lb.*

Delivery commitment may be later in some areas

- ☐ FedEx Priority Overnight — Next business morning
- ☑ FedEx Standard Overnight — Next business afternoon
- ☐ FedEx First Overnight — Earliest next business morning delivery to select locations
- ☐ FedEx 2Day* — Second business day
- ☐ FedEx Express Saver* — Third business day

* FedEx Envelope/Letter Rate not availat
Minimum charge: One-pound ra

4b Express Freight Service *Packages over 150 lb.*

Delivery commitment may be later in some are

- ☐ FedEx 1Day Freight* — Next business day
- ☐ FedEx 2Day Freight — Second business day
- ☐ FedEx 3Day Freight — Third business day

* Call for Confirmation: _____

5 Packaging * Declared value limit $5

- ☑ FedEx Envelope/Letter*
- ☐ FedEx Pak*
- ☐ Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling Include FedEx address in Section 3.

- ☐ SATURDAY Delivery — Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- ☐ SUNDAY Delivery — Available for FedEx Priority Overnight to select ZIP codes
- ☐ HOLD Weekday at FedEx Location — Not available with FedEx First Overnight
- ☐ HOLD Saturday at FedEx Locatio — Available for FedEx Pri Overnight and FedEx 2 to select locations

Does this shipment contain dangerous goods? One box must be checked.

- ☑ No
- ☐ Yes — As per attached Shipper's Declaration
- ☐ Yes — Shipper's Declaration not required
- ☐ Dry Ice — Dry Ice, 9, UN 1845 ____ x ____
- ☐ Cargo Aircraft Only

Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below.

- ☑ Sender — Acct. No. in Section 1 will be billed.
- ☐ Recipient
- ☐ Third Party
- ☐ Credit Card
- ☐ Cash/Che
- ☐ Obtain Recip. Acct. No.

Total Packages	Total Weight	Total Charges
1		

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

Credit Card Auth

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Call 1·800·Go·FedEx® (800-463-3339)

Visit our Web site at www.fedex.com

Rev. Date 3/00 • Part #155912G • ©1994–2000 FedEx • PRINTED IN U.S.A. GBFE 6/00

402